DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 4, 2016

Eyenez LLC
% Mr. Glen Feye
President
Accurate Consultants Inc.
3234 Ibis Street
San Diego, CA 92103

Re: K161727
Trade/Device Name: Eyenez Ophthalmic Camera
Regulation Number: 21 CFR 886.1120
Regulation Name: Opthalmic Camera
Regulatory Class: Class II
Product Code: HKI
Dated: August 22, 2016
Received: August 25, 2016

Dear Mr. Feye:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161727

Device Name
Eyenez Ophthalmic Camera, Model V200

Indications for Use *(Describe)*
The Eyenez V200 fundus camera is intended to be used to capture images of the retina of the eye.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 5

510k SUMMARY

This 510(k) summary is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

Establishment Registration Number (FEI): 3012121402

Address of Manufacturer:
Eyenez LLC
2619 E. Colorado Blvd Ste 100
Pasadena , CA 91107

Contact Person:
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Date Prepared: May 20, 2016

Trade or Proprietary Name: Eyenez Ophthalmic Camera

Common or Usual Name: V200 Ophthalmic camera

Classification Name: Camera, Ophthalmic, Ac-powered
(21 CFR 886.1120, Product Code HKI)

Predicate Device Identification: Optomed Smartscope M5 EY3 and M5 ES1 (K110986)- (aka. Volk Pictor Ret1)

Device Description:

The Eyenez Ophthalmic Camera is a handheld ophthalmic camera that combines a condensing lens with a built-in digital camera to capture a digital photograph of the retina and allow for the examination of the picture by an ophthalmic specialist. The Eyenez Ophthalmic Camera will allow users to capture images of the retina. Images may be saved to a flash memory card and also have connectivity towards PC using a USB interface. Device has a rechargeable battery.

Intended use and comparison to predicate devices:

The Eyenez V200 fundus camera is intended to be used to capture images of the retina of the eye.

Technological characteristics and comparison to predicate devices:

When The Eyenez Ophthalmic Camera is compared to the predicate device- Optomed Smartscope M5 with EY3 and ES1 (K110986), it can be seen that both devices have similar indications for use, and multiple similar technological features. Similar features include:

- Both devices store images to a flash memory card and have connectivity towards PC using a USB interface
- Both use rechargeable batteries
- Both devices use visible and infrared LED for illumination
- Devices have similar method of operation from a user's point of view. Both have graphic user interface and keyboard that is used for making adjustments before and during examination and fundus image capture
- Both store images in a JPEG format
- Both have a picture angle of over 40 degrees
- Both have diopter compensation of at least -20D to +20D
- Optical Equivalency and Radiation Safety measures since both have met the IEC60601-1 and IEC 60601-1-2.
- Both meet 15004-2:2007 standards for Group 1 instruments: ophthalmic instruments for which no potential light hazard exists.

Summary of clinical performance data:

A clinical study was performed, whereas retinal images taken with both the Eyenez Ophthalmic Camera and the predicate device- Optomed Smartscope M5 with EY3 and ES1 (K110986) (i.e. Volk Pictor Ret1) were compared and at least 90% equivalent in their ability to capture the presence or absence of retinal pathology. The clinical study enrolled a total of 34 subjects (19 diseased and 15 healthy); whom all met enrollment criteria. The diseased subjects included the following conditions: Macular Tear, Vitreous Macular Traction (VMT), Cystoid Macular Edema (with and without Atrophy), Ischemic Hemi-Retinal Vein Occlusion (HRVO), History of Retinal Laser Treatment, Non-Proliferative Diabetic Retinopathy (NPDR), Diabetic Macular Edema (DME), Quiescent proliferative diabetic retinopathy (QPDR), Epi-Retinal Membrane (ERM), Retinal Heme (Hemorrhage), Branch Retinal Vein Occlusion (BRVO), Dry Age-Related Macular Degeneration (AMD), Wet Age-Related Macular Degeneration (AMD), Lamellar Hole, Proliferative diabetic retinopathy (PDR), Neovascularization Elsewhere (NVE). The independent Ophthalmologist reviewing the retinal images concluded that the Eyenez OC Retina Camera images were comparable to the Volk Pictor OP on 33 patients (97%).

There are no major safety concerns.

Substantial Equivalence determination:

The data within this submission demonstrate that there are no significant differences between the application device and the predicate, indicating that the application device is safe, effective and substantially equivalent for marketing in the U.S. Any difference in the technology when compared to the predicate has been satisfactorily addressed by conformance to FDA and Internationally recognized safety consensus standards, as well as the company's design requirements and system validation. The Eyenez LLC Ophthalmic Camera is been deemed substantially equivalent by the Sponsor and no new or different questions of safety and effectiveness have been raised. The Eyenez LLC Ophthalmic Camera is as safe and effective as an ophthalmic camera, which is identical to the identified predicate device.